

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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Implantation or Injectable Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two approved new animal drug applications (NADA's) from Pfizer, Inc., to Phoenix Scientific, Inc.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Norman J. Turner, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0214.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, has informed FDA that it has transferred to Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, ownership of, and all rights and interests in NADA 065-110 for Pro-Pen G (penicillin G procaine) in Aqueous Suspension and NADA 065-498 for Pen BP-48 (penicillin G benzathine/procaine). Accordingly, the agency is amending the regulations in 21 CFR 522.1696a and 522.1696b to reflect the transfer of ownership. The agency is also taking the opportunity to restructure the regulation to reflect current format.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.1696a is revised to read as follows:

§ 522.1696a Penicillin G benzathine and penicillin G procaine sterile suspension.

(a) *Specifications.* Each milliliter of aqueous suspension contains penicillin G benzathine and penicillin G procaine, each equivalent to 150,000 units of penicillin G.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for the conditions of use in paragraph (d) of this section as follows:

(1) Nos. 000008, 000856, 000864, 010515, and 049185 for use as in paragraph (d)(1) of this section.

(2) Nos. 000856 and 049185 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(2)(iii) of this section.

(3) Nos. 000864, 010515, and 059130 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use—(1) Horses, dogs, and beef cattle—(i) Amount—(A) Beef cattle.* 2 milliliters per 150 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(B) *Horses*. 2 milliliters per 150 pounds of body weight intramuscularly. Repeat dosage in 48 hours.

(C) *Dogs*. 1 milliliter per 10 to 25 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use*. Treatment of bacterial infections susceptible to penicillin G.

(iii) *Limitations*. In beef cattle, treatment should be limited to two doses. Not for use in beef cattle within 30 days of slaughter. Do not use in horses intended for food purposes. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Beef cattle*—(i) *Amount*. 2 milliliters per 150 pounds of body weight subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use*. (A) Treatment of bacterial pneumonia (*Streptococcus* spp., *Corynebacterium pyogenes*, *Staphylococcus aureus*); upper respiratory infections such as rhinitis or pharyngitis (*Cpyogenes*); blackleg (*Clostridium chauvoei*).

(B) As in paragraph (d)(2)(ii)(A) of this section; and prophylaxis of bovine shipping fever in 300- to 500-pound beef calves.

(iii) *Limitations*. Limit treatment to two doses. Not for use within 30 days of slaughter.

3. Section 522.1696b is revised to read as follows.

§ 522.1696b Penicillin G procaine aqueous suspension.

(a) *Specifications*. Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) Nos. 010515, 053501, and 059130 for use as in paragraph (d) of this section.

(2) Nos. 000864 and 055529 for use as in paragraph (d)(2) of this section.

(c) *Related tolerances*. See § 556.510 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*. 10,000 units per pound body weight daily by intramuscular injection at 24-hour intervals. Continue treatment at least 48 hours after symptoms disappear.

(ii) *Indications for use*. Treatment of infections caused by penicillin-sensitive organisms.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle, sheep, swine, and horses*—(i) *Amount*. 3,000 units per pound body weight (1 milliliter per 100 pounds body weight) daily by intramuscular injection.

(A) For Nos. 000864, 010515, 053501, and 059130: Continue treatment at least 48 hours after symptoms disappear.

(B) For No. 055529: Continue treatment at least 1 day after symptoms disappear (usually 2 or 3 days).

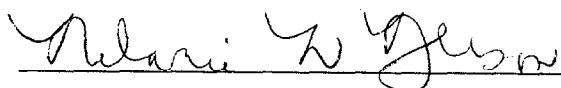
(ii) *Indications for use*. Treatment of cattle and sheep for bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*; swine for erysipelas caused by *Erysipelothrix insidiosa*; and horses for strangles caused by *Streptococcus equi*.

(iii) *Limitations*. Not for use in horses intended for food.

(A) For Nos. 000864, 010515, 053501, and 059130: Do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle. Milk that has been taken during treatment and for 48 hours after the last treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Nonruminating cattle (calves)—7, all other cattle—4, sheep—8, and swine—6.

(B) For No. 055529: Treatment should not exceed 4 consecutive days. Milk that has been taken during treatment and for 72 hours after the last treatment must not be used for food. Discontinue treatment for the following number of days before slaughter: Cattle—10, sheep—9, and swine—7.

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Melanie R. Berson,
Acting Deputy Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

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